

## REMARKS

Applicants have carefully reviewed the office action dated August 13, 2003. Claims 1-21, 30, 36, 42-46, and 50-54 are pending. Claims 1-20, 30, 36 and 42 are withdrawn from consideration. Claims 21, 43-46, and 50-54 have been rejected, and claim 21 has been amended.

Claims 21 and 50-54 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nash et al., U.S. Patent No. 6,080,170. Applicants respectfully traverse this rejection in light of the above amendment to claim 21.

As the Examiner stated in the most recent Office Action, a prior amendment to claim 21 was not correctly submitted, and was not therefore entered into the record. In response, claim 21 has been amended in compliance with 37 C.F.R. 1.121(c). Although the incorrectly entered amendment was not entered into the record, it appears as though the Examiner did consider the amendment, conducted a prior art search in light of the amendment, and responded to the limitations in the amendment. This is apparent due to the change in the rejection from a §102 rejection in the March 11, 2003 Office Action to a §103 rejection in the most recent Office Action. In addition, the Examiner responded to the incorrectly entered amendment by adding a paragraph addressing the question of the obviousness of advancing an aspirating catheter over a guidewire in view of Nash et al. Although the language of the incorrectly entered amendment and the current amendment differ, the Applicants assert that the content of the language is similar enough to alleviate the need for an additional prior art search.

The Applicants also assert that the prior correctly entered amendment (the current final paragraph of claim 21) would lack an antecedent basis without the currently amended

language. Specifically, the reference to “the aspirating catheter” lacks an antecedent basis, and the current amendment remedies this issue by referring to “an aspirating catheter.”

Because an additional prior art search should not be necessary and the current amendment is introduced in part to clarify the claim, the Applicants respectfully assert that the Examiner should consider the amendment.

In light of this amendment, Applicants respectfully assert that Nash et al. does not render the current invention unpatentable. In order for prior art to render a claim obvious, all of the elements of the claim must be taught or suggested in the prior art. *See* M.P.E.P. §2143.03. The method in claim 21 of the current invention, as amended, includes a limitation that the aspirating catheter be advanced over the guidewire from the point of introduction to a position where the distal end of the aspirating catheter is immediately proximal the region of interest. This element of claim 21 is not disclosed in Nash et al.

The current Office Action appears to be stating that this element of claim 21 is inherently performed in the procedures described in Nash et al. because the method in Nash et al. will likely include adjustments to the positioning of the catheter over the guidewire, and may include making small advances of the guide catheter over the guidewire. *See* August 13, 2003 Office Action, page 3. However, claim 21, as amended, recites advancing the aspirating catheter from the point of introduction to a position just proximal the region of interest. This is clearly different than making small adjustments in the position of the guide catheter over the guidewire, and thus Nash et al. does not disclose this element of claim 21.

Also, the use of a guide catheter in Nash et al. is different than the use of an aspirating catheter in the current invention. Notably, the guide catheter (and optional catheter 504) is the closest element disclosed by Nash et al. to the aspirating catheter of claim 21. Nash et al.

does not disclose advancing the guide catheter over the guidewire and positioning it proximal the region of interest as claimed in claim 21. Nash et al. discloses advancing the guidewire through the already positioned guide catheter. Significantly, the device disclosed by Nash et al. will not, in its normal and usual operation, perform the method of claim 21. A guide catheter is a large catheter having a curved distal end and is used to guide medical instruments through the aortic arch to a specific vessel requiring treatment. In its normal and usual operation, a guide catheter will be advanced and positioned prior to advancing any medical devices used to treat the region of interest. Nash et al., therefore, does not disclose each and every element of the claimed invention.

In addition, there is not a proper showing of a suggestion or motivation to modify the Nash et al. reference. "The proposed modification cannot change the principle of operation of a reference." *See* M.P.E.P. §2143.01. Such a change in principle of operation indicates a lack of suggestion or motivation to modify the reference. The method disclosed in Nash et al. is fundamentally different than the method recited in the claim 21. Specifically, introducing a guide catheter and then introducing a guidewire through the guide catheter is fundamentally different than introducing the guidewire first and an aspirating catheter second. Because a guidewire is much more flexible and smaller than a guide catheter, the introduction of a guidewire first will enable navigation through torturous paths or into the smaller vessels through which a guide catheter may not be able to navigate. Even after the introduction of the guide catheter, the guidewire will have to be advanced through the guide catheter and then through an additional length of vessel, after which additional adjustments may be required in the positioning of the guide catheter.

In contrast, the method of claim 21 recites advancing the guidewire past the region of interest, and then the aspirating catheter is advanced to a position just proximal the region of interest. Thus, the method disclosed in Nash et al. will require more steps and a different sequence steps than the current invention. Also, the method in Nash et al. will be more difficult to perform, will result in less precision than the current method, and likely will not be able to reach regions of interest in smaller vessels. The method used in the Nash et al. disclosure also seemingly teaches away from the current invention, in that the use of a large guide catheter is inconsistent with the objective of treating cites in smaller vessels. Because the principle of operation of the two methods is different and Nash et al. teaches away from the current invention, there is no suggestion or motivation for modifying the Nash et al. reference.

Because all of the elements of the current invention were not disclosed in the prior art, and because there is not a suggestion or motivation to modify the prior art, it is respectfully asserted that a *prima facie* case of obviousness has not been shown for claim 21. Because independent claim 21 is not obvious, then dependent claims 43-46 and 50-54 are also not obvious and include additional elements to distinguish them from the prior art.

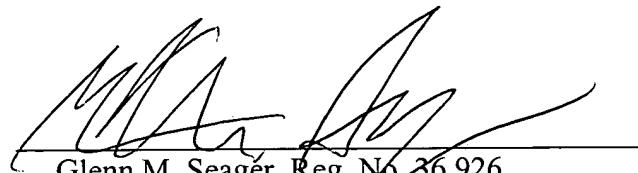
Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
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By their Attorney,

Date:

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